

## CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper referred to as being transmitted therewith) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on:

Date: 12-11-06By: [Signature]  
Winsome St Rose

IN RE APPLICATION OF:

Martin Dugas, et al.

SERIAL NO.: 10/575,805

PCT FILING DATE: NOVEMBER 4, 2004

FOR: METHOD FOR DISTINGUISHING  
T(11Q23)/MLL-POSITIVE LEUKEMIAS  
FROM T(11Q23)/MLL NEGATIVE  
LEUKEMIA

)

) EXAMINER: Unassigned

) ART UNIT: Unassigned

) Confirmation No. 3903

) DOCKET NO 22329-US

MISSING PARTS TRANSMITTAL

Mail Stop Missing Parts  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Notification of Missing Requirements Under 35 U.S.C 371 in the United States Designated/Elected Office mailed June 9, 2006, (copy attached), applicants hereby submit the following:

- ☒ An executed Oath and Declaration by the inventors in accordance to 37 C.F.R. 1.497 (a) and (b)
- ☒ Surcharge of \$130.00 as set forth in 37 CFR 1.16(e)
- ☒ Copy of the Notification of Missing Requirements Under 35 U.S.C 371 in the US DO/EO
- ☒ Statement Under 37 C.F.R. §1.821 –1.825
- ☒ CRF of the Sequence Listings
- ☒ Petition for a 4 month Extension of Time in the amount of \$1590.00

The Commissioner is hereby authorized to debit Deposit Account No. 50-0812 , in the amount of \$1720.00, or any additional fee or credit overpayment. A duplicate copy of this sheet is enclosed.

Date: 12/14/06

Respectfully Submitted,

Correspondence Address  
Roche Molecular Systems, Inc  
1145 Atlantic Avenue  
Alameda, CA 94501  
Tel: 510-814-2800  
Fax: 510-814-2973

[Signature]  
Robert W. Mann  
Reg. No. 48,555

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Martin Dugas, et al.

SERIAL NO.: 10/575,805

PCT FILING DATE: NOVEMBER 4, 2004

INVENTOR: METHOD FOR DISTINGUISHING  
T(11Q23)/MLL-POSITIVE  
LEUKEMIAS FROM T(11Q23)/MLL  
NEGATIVE LEUKEMIA

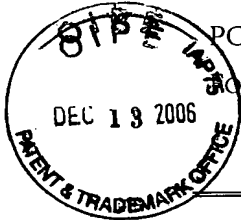
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) EXAMINER: Unassigned

) ART UNIT: Unassigned

) Confirmation No. 3903

) DOCKET NO 22329-US



Certification of Mailing Under 37 CFR § 1.10

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

I hereby certify that the following correspondences:

- ☒ Missing Parts Transmittal
- ☒ Oath and Declaration by the inventors in accordance to 37 C.F.R. 1.497 (a) and (b).
- ☒ Surcharge of \$130.00 as set forth in 37 CFR 1.16(e).
- ☒ Copy of the Notification of Missing Requirements Under 35 U.S.C 371 in the US DO/EO.
- ☒ Statement Under 37 C.F.R. § 1.821 – 1.825
- ☒ CRF of the Sequence Listings.
- ☒ Return receipt postcard, and
- ☒ Petition for a 4 month Extension of Time in the amount of \$1590.00

are being deposited with the United States Postal Service in an envelope on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
Winsome St Rose

12-11-06  
Date

Roche Molecular Systems, Inc.  
1145 Atlantic Avenue  
Alameda, CA 94501  
Tele: (510) 814-2800  
Fax: (510) 814-2973

12/15/2006 GFREY1 00000156 500812 10575805

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22329-US



UNITED STATES PATENT AND TRADEMARK OFFICE

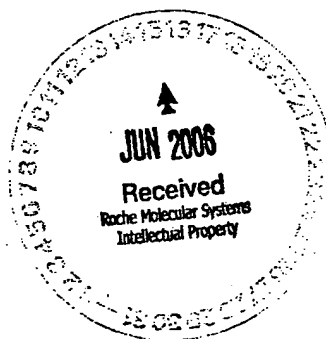
DEC 13 2006

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
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 Alexandria, Virginia 22313-1450  
 www.uspto.gov

Pct

|   |                                       |                               |
|---|---------------------------------------|-------------------------------|
| U.S. APPLICATION NUMBER NO.<br>✓ 10/575,805 | FIRST NAMED APPLICANT<br>Martin Dugas | ATTY. DOCKET NO.<br>✓ 22329US |
|---|---------------------------------------|-------------------------------|

22829  
 ROCHE MOLECULAR SYSTEMS INC  
 PATENT LAW DEPARTMENT  
 1145 ATLANTIC AVENUE  
 ALAMEDA, CA 94501



|   |                             |
|---|-----------------------------|
| INTERNATIONAL APPLICATION NO.<br>PCT/EP04/12462 |                             |
| I.A. FILING DATE<br>11/04/2004                  | PRIORITY DATE<br>11/04/2003 |

CONFIRMATION NO. 3903

371 FORMALITIES LETTER



\*OC000000019198008\*

Date Mailed: 06/09/2006

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 04/13/2006
- Copy of the International Search Report filed on 04/13/2006
- Preliminary Amendments filed on 04/13/2006
- Oath or Declaration filed on 05/26/2006
- Request for Immediate Examination filed on 04/13/2006
- U.S. Basic National Fees filed on 04/13/2006
- Substitute Specification filed on 04/13/2006
- Priority Documents filed on 04/13/2006
- Specification filed on 04/13/2006
- Claims filed on 04/13/2006
- Abstracts filed on 04/13/2006

COPY

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
  - each inventor name must be listed on each decl, if signing separate decl, you have 2 pgs., #4 Alexander Kolhmann, look as if the other inventor don't know that he is an inventor ,
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath

or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- **\$130 Surcharge.**
- This application clearly fails to comply with the requirements of 37 CFR 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.** Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951.
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

VONDA M WALLACE

Telephone: (703) 308-9140 EXT 225

PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/575,805                  | PCT/EP04/12462                | 22329US          |

FORM PCT/DO/EO/905 (371 Formalities Notice)